Respiratory Care Board of California

Laws & Regulations as they relate to

Home Respiratory Care

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RESPIRATORY CARE PRACTICE ACT
Business and Professions Code, Sections 3700 et.
Division 2, Chapter 8.3

Respiratory Care Scope of Practice

§ 3702. Practice of respiratory care; Components; "Respiratory care protocols"

Respiratory care as a practice means a health care profession employed under the supervision of a medical director in the therapy, management, rehabilitation, diagnostic evaluation, and care of patients with deficiencies and abnormalities which affect the pulmonary system and associated aspects of cardiopulmonary and other systems functions, and includes all of the following:

- (a) Direct and indirect pulmonary care services that are safe, aseptic, preventative, and restorative to the patient.
- (b) Direct and indirect respiratory care services, including but not limited to, the administration of pharmacological and diagnostic and therapeutic agents related to respiratory care procedures necessary to implement a treatment, disease prevention, pulmonary rehabilitative or diagnostic regimen prescribed by a physician and surgeon.
- (c) Observation and monitoring of signs and symptoms, general behavior, general physical response to respiratory care treatment and diagnostic testing and
- (1) determination of whether such signs, symptoms, reactions, behavior or general response exhibit abnormal characteristics;
- (2) implementation based on observed abnormalities of appropriate reporting or referral or respiratory care protocols, or changes in treatment regimen, pursuant to a prescription by a physician and surgeon or the initiation of emergency procedures.
- (d) The diagnostic and therapeutic use of any of the following, in accordance with the prescription of a physician and surgeon: administration of medical gases, exclusive of general anesthesia; aerosols; humidification; environmental control systems and baromedical therapy; pharmacologic agents related to respiratory care procedures; mechanical or physiological ventilatory support; bronchopulmonary hygiene; cardiopulmonary resuscitation; maintenance of the natural airways; insertion without cutting tissues and maintenance of artificial airways; diagnostic and testing techniques required for implementation of respiratory care protocols; collection of specimens of blood; collection of specimens from the respiratory tract; analysis of blood gases and respiratory secretions.
- (e) The transcription and implementation of the written and verbal orders of a physician and surgeon pertaining to the practice of respiratory care.

"Respiratory care protocols" as used in this section means policies and protocols developed by a licensed health facility through collaboration, when appropriate, with administrators, physicians and surgeons, registered nurses, physical therapists, respiratory care practitioners, and other licensed health care practitioners.

§ 3702.7. Mechanical and ventilatory support defined

Mechanical or physiological ventilatory support as used in subdivision (d) of Section 3702 includes, but is not limited to, any system, procedure, machine, catheter, equipment, or other device used in whole or in part, to provide ventilatory or oxygenating support.

Medical Director Supervision

§ 3703. Settings for respiratory care

- (a) The settings in which respiratory care may be practiced include licensed health care facilities, hospitals, clinics, ambulatory or home health care, physicians' offices, and public or community health services. Respiratory care may also be provided during the transportation of a patient, and under any circumstances where an emergency necessitates respiratory care.
- (b) The practice of respiratory care shall be performed under the supervision of a medical director in accordance with a prescription of a physician and surgeon or pursuant to respiratory care protocols as specified in Section 3702.

§ 3704. Definitions

As used in this chapter, these terms shall be defined as follows:

- (a) "Board" means the Respiratory Care Board of California.
- (b) "Department" means the Department of Consumer Affairs.
- (c) "Medical director" means a physician and surgeon who is a member of a health care facility's active medical staff and who is knowledgeable in respiratory care.
 - (d) "Respiratory care" includes "respiratory therapy" or "inhalation therapy," where those terms mean respiratory care.
 - (e) "Respiratory therapy school" means a program reviewed and approved by the board.

Mandatory Reporting of Unlicensed Practice And Other Violations

§ 3758. Report on suspension or termination for cause

- (a) Any employer of a respiratory care practitioner shall report to the Respiratory Care Board the suspension or termination for cause of any practitioner in their employ. The reporting required herein shall not act as a waiver of confidentiality of medical records. The information reported or disclosed shall be kept confidential except as provided in subdivision (c) of Section 800, and shall not be subject to discovery in civil cases.
- (b) For purposes of the section, "suspension of termination for cause" is defined to mean suspension or termination from employment for any of the following reasons:
 - (1) Use of controlled substances or alcohol to such an extent that it impairs the ability to safely practice respiratory care.
 - (2) Unlawful sale of controlled substances or other prescription items.
 - (3) Patient neglect, physical harm to a patient, or sexual contact with a patient.
 - (4) Falsification of medical records.
 - (5) Gross incompetence or negligence.
 - (6) Theft from patients, other employees, or the employer.
- (c) Failure of an employer to make a report required by this section is punishable by an administrative fine not to exceed ten thousand dollars (\$10,000) per violation.

§ 3758.5. Reporting violations

If a licensee has knowledge that another person may be in violation of, or has violated, any of the statutes or regulations administered by the board, the licensee shall report this information to the board in writing and shall cooperate with the board in furnishing information or assistance as may be required.

§ 3759. No civil penalties

Pursuant to Section 43.8 of the Civil Code, no person shall incur any civil penalty as a result of making any report required by this chapter.

License Required to Practice Respiratory Care

§ 3760. Unauthorized practice or use of title

- (a) Except as otherwise provided in this chapter, no person shall engage in the practice of respiratory care, respiratory therapy, or inhalation therapy. For purposes of this section, engaging in the practice of respiratory care includes, but is not limited to, representations by a person whether through verbal claim, sign, advertisement, letterhead, business card, or other representation that he or she is able to perform any respiratory care service, or performance of any respiratory care service.
- (b) No person who is unlicensed or whose respiratory care practitioner license has been revoked or suspended, or whose license is not valid shall engage in the practice of respiratory care during the period of suspension or revocation, even though the person may continue to hold a certificate or registration issued by a private certifying entity.
- (c) Except as otherwise provided in this chapter, no person may represent himself or herself to be a respiratory care practitioner, a respiratory therapist, a respiratory care technician, or an inhalation therapist, or use the abbreviation or letters "R.C.P.," "R.P.," "R.T.," or "I.T.," or use any modifications or derivatives of those abbreviations or letters without a current and valid license issued under this chapter.
- (d) No respiratory care practitioner applicant shall begin practice as a "respiratory care practitioner applicant" pursuant to Section 3739 until the applicant meets the applicable requirements of this chapter and obtains a valid work permit.

§ 3761. License required for practice

- (a) No person may practice respiratory care or represent himself or herself to be a respiratory care practitioner in this state, without a valid license granted under this chapter, except as otherwise provided in this chapter.
- (b) No person or corporation shall knowingly employ a person who holds himself or herself out to be a respiratory care practitioner without a valid license granted under this chapter, except as otherwise provided in this chapter.

§ 3763. Violations as misdemeanors; Punishment

Any person who violates any of the provisions of this chapter shall be guilty of a misdemeanor punishable by a fine not exceeding one thousand dollars (\$1,000) or imprisonment in a county jail not exceeding six months, or both, for each offense.

Licensure Exemptions

§ 3765. Acts not prohibited

This act does not prohibit any of the following activities:

- (a) The performance of respiratory care that is an integral part of the program of study by students enrolled in approved respiratory therapy training programs.
- (b) Self-care by the patient or the gratuitous care by a friend or member of the family who does not represent or hold himself or herself out to be a respiratory care practitioner licensed under the provisions of this chapter.
- (c) The respiratory care practitioner from performing advances in the art and techniques of respiratory care learned through formal or specialized training.
- (d) The performance of respiratory care by paramedical personnel who have been formally trained in these modalities and are duly licensed under the provisions of an act pertaining to their speciality.
- (e) Respiratory care services in case of an emergency. "Emergency," as used in this subdivision, includes an epidemic or public disaster.
 - (f) Persons from engaging in cardiopulmonary research.
- (g) Formally trained licensees and staff of child day care facilities from administering to a child inhaled medication as defined in Section 1596.798 of the Health and Safety Code.
- (h) The performance by a person employed by a home medical device retail facility or by a home health agency licensed by the State Department of Health Services of specified, limited, and basic respiratory care or respiratory care related services that have been authorized by the Board.

Employer & Unlicensed Personnel: Citation and Fine

§ 3766. Unlicensed Personnel - Citation and Fines

- (a) The board may issue a citation containing an order of abatement and civil penalties against a person who acts in the capacity of, or engages in the business of, a respiratory care practitioner in this state without having a license in good standing issued pursuant to this chapter.
- (b) The board may issue a citation containing an order of abatement and civil penalties against a person employing or contracting with a person who acts in the capacity of, or engages in the business of, a respiratory care practitioner in this state without having a license in good standing issued pursuant to this chapter.

§ 3767. Unlicensed Personnel - Cite and Fine Issuance

- (a) The board shall issue a citation to a person and to his or her employer or contractor, if, upon inspection or investigation, either upon complaint or otherwise, the following conditions are met:
- (1) The board has probable cause to believe that the person is acting in the capacity of, or engaging in the practice of, a respiratory care practitioner in this state without having a license in good standing issued pursuant to this chapter.
 - (2) The person is not otherwise exempted from the provisions of this chapter.
 - (b) Each citation issued pursuant to subdivision (a) shall meet all of the following requirements:
 - (1) Be in writing and describe with particularity the basis of the citation.
- (2) Contain an order of abatement and an assessment of a civil penalty in an amount not less than two hundred dollars (\$200) nor more than fifteen thousand dollars (\$15,000).
- (c) A person served with a citation may appeal to the board within 15 calendar days after service of the citation with respect to any of the following:
 - (1) The violations alleged.
 - (2) The scope of the order of abatement.
 - (3) The amount of the civil penalty assessed.
- (d) If, within 15 calendar days after service of the citation, the person cited fails to notify the board that he or she intends to appeal the citation, the citation shall be deemed a final order of the board and not subject to review by any court or agency. The board may extend the 15-day period for good cause.
- (e) (1) If a person cited under this section notifies the board in a timely manner that he or she intends to contest the citation, the board shall afford an opportunity for a hearing.
- (2) The board shall thereafter issue a decision, based on findings of fact, affirming, modifying, or vacating the citation, or directing other appropriate relief.
- (f) With the approval of the board, the executive officer shall prescribe procedures for the issuance and appeal of a citation and procedures for a hearing under this section. The board shall adopt regulations covering the assessment of a civil penalty that shall give due consideration to the gravity of the violation, and any history of previous violations.
 - (g) The sanctions authorized under this section shall be separate from and in addition to, any other civil or criminal remedies.

§ 3768. Unlicensed Personnel - Fine Collections

- (a) After the exhaustion of the review procedures provided for in Section 3767, and as adopted by regulation, the board may apply to the appropriate superior court for both of the following:
 - (1) A judgment in the amount of the civil penalty.
 - (2) An order compelling the cited person to comply with the order of abatement.
 - (b) The application described in subdivision (a) shall include a certified copy of the final order of the board.
- (c) The application described in subdivision (a) shall constitute a sufficient showing to warrant the issuance of the judgment and order.
 - (d) The board may employ collection agencies or other methods in order to collect civil penalties.

CALIFORNIA CODE OF REGULATIONS Title 16, Division 13.6

Definitions

§ 1399.302. Definitions

Unless the context otherwise requires, the following definitions shall apply:

- (a) "Board" means the Respiratory Care Board of California.
- (b) "B&PC" means the Business and Professions Code.
- (c) "Act" means the Respiratory Care Practice Act.
- (d) "Direct Supervision" means assigned to a currently licensed respiratory care practitioner who is on duty and immediately available in the assigned patient area.
- (e) "Employer" means any company, corporation, partnership, health maintenance organization, or any other entity or person that employs or contracts with, one or more respiratory care practitioners or unlicensed personnel to provide respiratory care services as provided in the Act.
- (f) "Licensed Home Care Employer" means a Home Medical Device Retail Facility, Home Health Agency, or any home care provider licensed by the Department of Health Services or its successor.
 - (g) "Regulations" means Division 13.6 of Title 16 of the California Code of Regulations.
- (h) "Unlicensed Personnel" means an individual not otherwise authorized or exempt to provide respiratory care services except as provided for in Article 6.

Unlicensed Personnel Services

\$1399.360. Unlicensed Personnel Services; Home Care

- (a) Unlicensed personnel (UP) may perform limited and basic respiratory care or respiratory care related services identified in subdivisions (b) and (c) in the home setting or for the purposes of patient transfer to the home setting, provided the following conditions are met:
 - (1) The UP is providing services through his or her employment with a Licensed Home Care Employer (LHCE);
- (2) The UP has been provided initial training, ongoing in-service education, and periodic competency testing specific to each service and equipment-type by either a California licensed respiratory care practitioner (RCP) or other qualified licensed personnel, in accordance with his or her scope of practice, and documentation of such training, education and testing is maintained by the LHCE for a period of four years, and
- (3) The LHCE ensures that the patient, the patient's family, or the patient's caregiver(s) are advised prior to or at the time equipment or supplies are delivered, that a RCP or other qualified licensed personnel, in accordance with his or her scope of practice, shall provide follow up checks, by telephone or in-person as appropriate, at the request of the patient or the patient's family, caregiver, or physician, or any person who has had contact with the patient, or as otherwise directed by a plan of care, and such services are provided accordingly.
 - (b) In accordance with this section and as it relates to:
 - positive airway pressure (with or without a back-up rate) devices and supplies;
 - intermittent positive pressure breathing devices and supplies;
 - ventilatory devices and supplies;
 - nasotracheal or tracheal suctioning devices and supplies;
 - apnea monitors and alarms and supplies;
 - tracheostomy care devices and supplies;
 - respiratory diagnostic testing devices and supplies, including but not limited to pulse oximetry, CO2 monitoring, and spirometry devices and supplies;

- pulse-dose type or demand conserving oxygen delivery devices or high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen, and
- any other respiratory care equipment and supplies not identified in subdivisions (b) and (c),
- (1) UP may:
 - (A) Deliver equipment and supplies;
- (B) Instruct the patient, the patient's family or the patient's caregiver(s) on how to order equipment and supplies and the telephone number to call 24 hours a day, 7 days a week, in case of emergency in which a live person will be available to respond;
- (C) Set up equipment to the extent that the set-up is not dependent upon or influenced by any written or oral communication with the patient or the patient's family, caregiver(s) or physician (with the exception of identifying a physical location in the home for set-up), and
- (D) Provide instruction to the patient, the patient's family or the patient's caregiver(s) limited to the mechanical operation of the equipment (e.g. switch, knob, and dial locations) or the general use of equipment or supplies.
 - (2) UP are prohibited from:
- (A) Setting up equipment to an extent that it constitutes patient care such as applying any device to the patient or making any adjustment or taking any action that requires or is dependent upon or influenced by any written or oral communication with the patient or the patient's family, caregiver(s) or physician;
- (B) Providing any instruction to an extent that it constitutes patient care, such as instruction in the operation or use of the equipment for the purpose of deriving an intended medical benefit or instruction in the clinical application of equipment and/or supplies;
 - (C) Performing any level of clinical assessment of the patient;
 - (D) Directly engaging in any discussion of clinical care plans, therapy, prescriptions, or clinical application;
 - (E) Touching the patient for the purposes of making an assessment or placing any device upon the patient, and
 - (F) Providing any service that is not expressly authorized by this section.
- (c) In accordance with this section and as it relates to oxygen delivery systems and prefilled cylinders, with the exception of pulse-dose or demand conserving oxygen systems and high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen,
 - (1) UP may:
 - (A) Deliver equipment and supplies;
- (B) Instruct the patient, the patient's family or the patient's caregiver(s) on how to order oxygen equipment and supplies and the telephone number to call 24 hours a day, 7 days a week, in case of emergency in which a live person will be available to respond;
- (C) Instruct the patient, the patient's family or the patient's caregiver(s) in the proper and safe operation of oxygen equipment including:
 - (i) equipment set-up for the purpose of making the equipment patient-ready;
 - (ii) connecting disposable tubing, cannulas, and masks;
 - (iii) verification of oxygen flow;
 - (iv) demonstration to the patient of prescribed flow rate(s);
 - (v) connection and cleaning of oxygen humidifying equipment and devices;
 - (vi) use of portable back-up oxygen cylinders and equipment, and
 - (vii) removal and disposition of disposable tubing, cannulas, and masks, and
 - (D) Use a mock, self-demonstration as a method of instruction for subdivision (c)(1)(C).
- (E) Conduct regular in-home evaluations and gather information from the patient and home setting pertaining to the set-up, instruction, and provision of information as described in this subdivision for the use of the prescribing physician.
 - (2) UP are prohibited from:
 - (A) Direct administration of home oxygen;
 - (B) Handling or adjusting home oxygen equipment while it is in use by the patient or on the patient;
- (C) Touching the patient or placing any device upon the patient while engaged in the set-up and instruction of equipment, including, but not limited to, applying a cannula or performing an oximetry evaluation or oxygen saturation test, and
- (D) Directly engaging in any discussion of clinical care plans, oxygen therapy or any modifications of physician prescribe equipment, dosages, or instructions or clinical applications.

Respiratory Care Board of California

Unlicensed Personnel in Home Care



Summary of NEW California Laws Related to Respiratory Care Providers

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Medical device retailers or any home care provider who provides respiratory care equipment or respiratory care in the home are subject to the following regulations. Any person or employer who is in violation of these regulations should be reported to the Respiratory Care Board of California.

- Unlicensed Personnel (UP) must be employed by a Home Medical Device Retail Facility or Home Health Agency licensed by the Department of Health Services
- UP must have regular training and be competency tested to each service and equipment-type by either a
 licensed respiratory care practitioner (RCP) or other qualified licensed personnel. Documentation of such
 must be retained by the employer for four years
- The employer must ensure that the patient, the patient's family, or the patient's caregiver(s) are advised prior to or at the time equipment or supplies are delivered, that a RCP or other qualified licensed personnel, shall provide follow up checks upon their request or in accordance with the plan of care
- UP may deliver equipment and supplies
- UP <u>may</u> instruct the patient, the patient's family or the patient's caregiver(s) on how to order equipment and supplies and the telephone number to call 24 hours a day, 7 days a week, in case of emergency in which a live person will be available to respond

All Respiratory Care Devices

(except certain oxygen delivery systems and prefilled cylinders requiring simple mask and cannula)

As it relates to the following equipment and supplies for:

- positive airway pressure (with or without a back-up rate) devices
- intermittent positive pressure breathing devices
- ventilatory devices
- nasotracheal or tracheal suctioning devices
- apnea monitors and alarms
- tracheostomy care devices
- respiratory diagnostic testing devices and supplies, including but not limited to pulse oximetry, CO2 monitoring, and spirometry devices
- pulse-dose type or demand conserving oxygen delivery devices or high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen
- any other respiratory care equipment and supplies not otherwise identified
- UP <u>may</u> set up equipment to the extent that the set-up is not dependent upon or influenced by any written or oral communication with the patient or the patient's family, caregiver(s) or physician (with the exception of identifying a physical location in the home for set-up)
- UP <u>may</u> provide instruction to the patient, the patient's family or the patient's caregiver(s) limited to the mechanical operation of the equipment (e.g. switch, knob, and dial locations) or the general use of equipment or supplies

- UP are *prohibited* from setting up equipment to an extent that it constitutes patient care (such as applying any device to the patient or making any adjustment or taking any action that requires or is dependent upon or influenced by any written or oral communication with the patient or the patient's family, caregiver(s) or physician)
- UP are *prohibited* from providing any instruction to an extent that it constitutes patient care (such as instruction in the operation or use of the equipment for the purpose of deriving an intended medical benefit or instruction in the clinical application of equipment and/or supplies)
- UP are *prohibited* from performing any level of clinical assessment of the patient
- UP are *prohibited* from directly engaging in any discussion of clinical care plans, therapy, prescriptions, or clinical application
- UP are *prohibited* from touching a patient for the purposes of making an assessment or placing any device upon the patient
- UP are *prohibited* from providing any service that is not expressly authorized by the Respiratory Care Board

Oxygen Delivery Systems & Prefilled Cylinders

As it relates to oxygen delivery systems and prefilled cylinders, with the exception of pulse-dose or demand conserving oxygen systems and high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen:

- UP <u>may</u> instruct the patient, the patient's family or the patient's caregiver(s) in the proper and safe operation of oxygen equipment including:
 - (i) equipment set-up for the purpose of making the equipment patient-ready
 - (ii) connecting disposable tubing, cannulas, and masks
 - (iii) verification of oxygen flow
 - (iv) demonstration to the patient of prescribed flow rate(s)
 - (v) connection and cleaning of oxygen humidifying equipment and devices
 - (vi) use of portable back-up oxygen cylinders and equipment
 - (vii) removal and disposition of disposable tubing, cannulas, and masks
- UP may use a mock, self-demonstration as a method of instruction
- UP <u>may</u> conduct regular in-home evaluations and gather information from the patient and home setting pertaining to the set-up, instruction, and provision of information as described in this subdivision for the use of the prescribing physician
- UP are *prohibited* from direct administration of home oxygen
- UP are *prohibited* from handling or adjusting home oxygen equipment while it is in use by the patient or on the patient
- UP are *prohibited* from touching the patient or placing any device upon the patient while engaged in the setup and instruction of equipment, including, but not limited to, applying a cannula or performing an oximetry evaluation or oxygen saturation test
- UP are *prohibited* from directly engaging in any discussion of clinical care plans, oxygen therapy or any modifications of physician prescribed equipment, dosages, or instructions or clinical applications